15 December 2022
EMA/CHMP/931797/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Spikevax

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On 15 December 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Spikevax. The marketing authorisation holder for this medicinal product is Moderna Biotech Spain, S.L.

The CHMP adopted an extension to an existing indication to include use of Spikevax and Spikevax bivalent Original/Omicron BA.1 as a booster in children aged 6 to 11 years. For information, the full indications for Spikevax and Spikevax bivalent Original/Omicron BA.1 will be as follows[2]:

> Spikevax is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 6 months of age and older.
>
> Spikevax bivalent Original/Omicron BA.1 is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals ~~12~~ **6** years of age and older who have previously received at least a primary vaccination course against COVID 19 (see sections 4.2 and 5.1).
>
> The use of this vaccine should be in accordance with official recommendations.

For information, the indications for other compositions of the vaccine are provided in the summary of product characteristics (SmPC) for Spikevax.

Detailed recommendations for the use of this product will be described in the updated SmPC, which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] New text in bold, removed text as strikethrough

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